

REMARKS

Claims 1 to 94 have been cancelled. Claim 95 is pending. Claim 95 stands rejected under 35 U.S.C. 102(b) as being anticipated by Tomasi et. al. (Journal of Experimental Medicine, 1965, Vol. 121, pp. 101-125). New claims 96 to 109 have been added. Reconsideration of the subject patent application is respectfully requested.

Claim 95 has been amending adding limitations to the body of the claim to distinguish from prior art.

Paragraph number references are with respect to the published patent application US 2002/0006630. General methods for handling, growing and counting cells are given in example 1 (paragraphs [0211] to [0243]) and are well known in the art. Cell growth promoting conditions are defined in paragraph [0022]. The newly added claims are fully supported in the application and no new matter has been added. The scope of the new claims falls within the selected invention of the original restriction requirement. Specific support for each newly added claim is given in subsequent paragraphs.

Anticipation:

Claim 95 was rejected for being anticipated by Tomasi et. al. (Journal of Experimental Medicine, 1965, Vol. 121, pp. 101-125)). Tomasi disclosed carrying out immunoglobulin quantitative determination by utilizing "an antiserum specific for the component to be quantitated is mixed with 1 per cent agar and poured into Ouchterlony plates. The test antigen is placed in the well and after incubation for 24 hours at 37°C the diameter of the resulting ring is measured. The concentration of antigen is determined by reference to a standard curve relating ring diameters to concentrations." This is very different from the method disclosed in the specification and now claimed in amended claim 95. As presently claimed, the method utilizes a comparison with positive controls of known concentrations of immunoglobulin inhibitors, information clearly not taught or

suggested by Tomasi. The method of this claim is also specific for immunoglobulins that are inhibitors of cell growth, whereas Tomasi teaches only generally quantitation of immunoglobulins. We respectfully assert that the method of Tomasi does not anticipate the amended claimed method of claim 95. Specific support for the amendments to claim 95 can be found in paragraphs [0304], [0508] and Table 1, and more generally in paragraphs [0255] to [0302] and [556] to [0578].

New Claims:

Claims 96 and 97 provide a novel method for determining an important property with respect to cancer treatment (see paragraph [0640]). Paragraphs [0537] and [0549] describe the use of IgA and IgM as inhibitors of cell growth in steroid hormone responsive cells. Utilization of these inhibitors according to the claimed method enables the testing of other cells for the same type of mediator response, i.e. cell growth inhibition. The data provided in FIG. 62 displays a typical response between a cell sample untreated with IgM (0 ug/ml of IgM) and a cell sample treated with IgM (>20 ug/mL of IgM). A person of ordinary skill in the art would recognize the significance of a comparison of the results of a negative control to a test sample containing the substance to be assessed. This person would also be capable of carrying out such a comparison without undue experimentation. The meaning of significant increases in cell population doubling is supported in paragraph [0241].

Claims 98 to 101 are directed to a novel method of assessing estrogenic activity of a substance by utilizing the discovery of the inhibition of growth of steroid hormone-responsive cancer cells by immunoglobulins. These claims are supported by details provided especially in paragraphs [0332] and [0340], as well as in the rest of Example 7, paragraphs [0317] to [0328] of the published patent application. In particular, in paragraph [0332], the substance being tested is Phenol Red for estrogenic activity, but the method of testing is applicable to other substances as stated in the first line of paragraph [0340]: "The studies of the effects of phenol red or its lipophilic impurities demonstrate

the usefulness of the presently disclosed methods for the assessment of estrogenic and androgenic activity of commercially prepared materials, substances present or extracted from environmental or food sources or other sources that are thought to contain such activities.” The other paragraphs details the method used to carry out the studies. A person of ordinary skill in the art would recognize that comparing the results of a negative control to a test containing the substance to be assessed is common. The meaning of significant increase in cell population doubling is supported in paragraph [0241].

Claims 102 to 109 are dependent on claim 95. These dependent claims detail specific cell lines or groups of cell lines that have been enumerated in the Markush group in claim 95.

Respectfully submitted,

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